According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0579-0036. The time required to complete this information collection is estimated to average 2 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

OMB APPROVED
0579-0036
Exp.: 10/31/2018

This report is required by law (7 U.S.C. 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

Interagency Report Control
No. 0180-DOA-AN

Fiscal Year 2013

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. REGISTRATION NUMBER
85-F-0002

2. HEADQUARTERS RESEARCH FACILITY *(Name, address, and telephone number as registered with USDA, include ZIP Code)*

LOS ALAMOS NATIONAL LABORATORY
P. O. Box 1663 Mailstop K404

LOS ALAMOS, NM 87545

3. REPORTING FACILITY *(List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets, if necessary.)*

FACILITY LOCATIONS *(Sites)*

(b)(7)(F)

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY *(Attach additional sheets, if necessary, or use APHIS FORM 7023A.)*

A. Animals Covered By The Animal Welfare Regulations	**B.** Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	**C.** Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	**D.** Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	**E.** Number of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. *(An explanation of the procedures producing pain or distress on these animals and the reasons such drugs were not used must be attached to this report.)*	**F.** TOTAL NUMBER OF ANIMALS **(Cols. C + D + E)**
4. Dogs	0	0	0	0	0
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	0	0	0	0
7. Hamsters	0	0	0	0	0
8. Rabbits	0	0	0	0	0
9. Non-human Primates	0	0	0	0	0
10. Sheep	0	0	0	0	0
11. Pigs	0	0	0	0	0
12. Other Farm Animals					
13. Other Animals	0	59	0	0	59

ASSURANCE STATEMENTS

1.) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.

2.) Each principal investigator has considered alternatives to painful procedures.

3.) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). **A summary of all such exceptions is attached to this annual report.** In addition to identifying the IACUC approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.

4.) The attending veterinarian for this research facility has appropriate authority to ensure the provisions of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL

(*Chief Executive Officer (C.E.O.) or Legally Responsible Institutional Official (I.O.)*)

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

SIGNATURE OF C.E.O. OR I.O.	NAME AND TITLE OF C.E.O. OR I.O. *(Type or Print)*	DATE SIGNED
(b)(6), (b)(7)(c)		17-JAN-2014

According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0579-0036. The time required to complete this information collection is estimated to average 2 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

OMB APPROVED
0579-0036

This report is required by law (7 U.S.C. 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

Interagency Report Control No. 0180-DOA-AN

Fiscal Year 2013

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

CONTINUATION SHEET FOR ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. REGISTRATION NUMBER
85-F-0002

2. HEADQUARTERS RESEARCH FACILITY *(Name, address, and telephone number as registered with USDA, include ZIP Code)*
LOS ALAMOS NATIONAL LABORATORY
P. O. Box 1663 Mailstop K404

LOS ALAMOS, NM 87545

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY *(Attach additional sheets if necessary or use this form.)*

A. Animals Covered By The Animal Welfare Regulations	**B.** Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	**C.** Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	**D.** Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	**E.** Number of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. *(An explanation of the procedures producing pain or distress on these animals and the reasons such drugs were not used must be attached to this report.)*	**F.** TOTAL NUMBER OF ANIMALS **(Cols. C + D + E)**
WILD RODENTS	0	59	0	0	59

ASSURANCE STATEMENTS

1.) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.

2.) Each principal investigator has considered alternatives to painful procedures.

3.) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). **A summary of all such exceptions is attached to this annual report.** In addition to identifying the IACUC approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.

4.) The attending veterinarian for this research facility has appropriate authority to ensure the provisions of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL

(*Chief Executive Officer (C.E.O.) or Legally Responsible Institutional Official (I.O.)*)

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

(b)(6), (b)(7)(c) [redacted]

DATE SIGNED
17-JAN-2014

APHIS FORM 7023A
AUG 2013

According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0579-0036. The time required to complete this information collection is estimated to average 2 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

OMB APPROVED
0579-0036
Exp.: 10/31/2018

This report is required by law (7 U.S.C. 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

Interagency Report Control
No. 0180-DOA-AN

Fiscal Year 2013

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. REGISTRATION NUMBER
85-F-0003

2. HEADQUARTERS RESEARCH FACILITY *(Name, address, and telephone number as registered with USDA, include ZIP Code)*

ALAMOGORDO PRIMATE FACILITY
BOX 956, NEW MEXICO AVENUE

HOLLOMAN AFB, NM 88330

3. REPORTING FACILITY *(List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets, if necessary.)*

FACILITY LOCATIONS *(Sites)*

(b)(7)(F)

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY *(Attach additional sheets, if necessary, or use APHIS FORM 7023A.)*

A. Animals Covered By The Animal Welfare Regulations	**B.** Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	**C.** Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	**D.** Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	**E.** Number of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. *(An explanation of the procedures producing pain or distress on these animals and the reasons such drugs were not used must be attached to this report.)*	**F.** TOTAL NUMBER OF ANIMALS **(Cols. C + D + E)**
4. Dogs	0	0	0	0	0
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	0	0	0	0
7. Hamsters	0	0	0	0	0
8. Rabbits	0	0	0	0	0
9. Non-human Primates	171	0	0	0	0
10. Sheep	0	0	0	0	0
11. Pigs	0	0	0	0	0
12. Other Farm Animals					
13. Other Animals					

ASSURANCE STATEMENTS

1.) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.

2.) Each principal investigator has considered alternatives to painful procedures.

3.) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). **A summary of all such exceptions is attached to this annual report.** In addition to identifying the IACUC approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.

4.) The attending veterinarian for this research facility has appropriate authority to ensure the provisions of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL

(*Chief Executive Officer (C.E.O.) or Legally Responsible Institutional Official (I.O.)*)

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

SIGNATURE OF C.E.O. OR I.O.	**NAME AND TITLE OF C.E.O. OR I.O.** *(Type or Print)*	**DATE SIGNED**
(b)(6), (b)(7)(c)		25-OCT-2013

According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0579-0036. The time required to complete this information collection is estimated to average 2 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

OMB APPROVED
0579-0036
Exp.: 10/31/2018

This report is required by law (7 U.S.C. 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

Interagency Report Control No. 0180-DOA-AN

Fiscal Year 2013

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. REGISTRATION NUMBER
85-R-0002

2. HEADQUARTERS RESEARCH FACILITY *(Name, address, and telephone number as registered with USDA, include ZIP Code)*

UNIVERSITY OF NEW MEXICO - MAIN CAMPUS
Office of A C Compliance 1 Univ of N M
Health Sciences Center, BRFG37H, MSC 08 4560
ALBUQUERQUE, NM 87131

3. REPORTING FACILITY *(List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets, if necessary.)*

FACILITY LOCATIONS *(Sites)*

(b)(7)(F)

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY *(Attach additional sheets, if necessary, or use APHIS FORM 7023A.)*

A. Animals Covered By The Animal Welfare Regulations	**B.** Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	**C.** Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	**D.** Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	**E.** Number of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. *(An explanation of the procedures producing pain or distress on these animals and the reasons such drugs were not used must be attached to this report.)*	**F.** TOTAL NUMBER OF ANIMALS **(Cols. C + D + E)**
4. Dogs	0	0	0	0	0
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	0	0	0	0
7. Hamsters	80	31	0	0	31
8. Rabbits	0	0	0	0	0
9. Non-human Primates	0	0	0	0	0
10. Sheep	0	0	0	0	0
11. Pigs	0	0	0	0	0
12. Other Farm Animals					
13. Other Animals	203	51	0	0	51

ASSURANCE STATEMENTS

1.) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.

2.) Each principal investigator has considered alternatives to painful procedures.

3.) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). **A summary of all such exceptions is attached to this annual report.** In addition to identifying the IACUC approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.

4.) The attending veterinarian for this research facility has appropriate authority to ensure the provisions of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL

(*Chief Executive Officer (C.E.O.) or Legally Responsible Institutional Official (I.O.)*)

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

SIGNATURE OF C.E.O. OR I.O.	**NAME AND TITLE OF C.E.O. OR I.O.** *(Type or Print)*	**DATE SIGNED**
(b)(6), (b)(7)(c)		27-MAR-2014

APHIS FORM 7023
JUL 2013

According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0579-0036. The time required to complete this information collection is estimated to average 2 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

OMB APPROVED
0579-0036

This report is required by law (7 U.S.C. 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

Interagency Report Control No. 0180-DOA-AN

Fiscal Year 2013

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

CONTINUATION SHEET FOR ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. REGISTRATION NUMBER
85-R-0002

2. HEADQUARTERS RESEARCH FACILITY *(Name, address, and telephone number as registered with USDA, include ZIP Code)*

UNIVERSITY OF NEW MEXICO - MAIN CAMPUS
Office of A C Compliance 1 Univ of N M
Health Sciences Center, BRFG37H, MSC 08 4560
ALBUQUERQUE, NM 87131

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY *(Attach additional sheets if necessary or use this form.)*

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. *(An explanation of the procedures producing pain or distress on these animals and the reasons such drugs were not used must be attached to this report.)*	F. TOTAL NUMBER OF ANIMALS **(Cols. C + D + E)**
SHORT-TAILED OPOSSUMS	203	51	0	0	51

ASSURANCE STATEMENTS

1.) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.

2.) Each principal investigator has considered alternatives to painful procedures.

3.) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). **A summary of all such exceptions is attached to this annual report.** In addition to identifying the IACUC approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.

4.) The attending veterinarian for this research facility has appropriate authority to ensure the provisions of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL

(*Chief Executive Officer (C.E.O.) or Legally Responsible Institutional Official (I.O.)*)

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

(b)(6), (b)(7)(c)

[redacted]

DATE SIGNED
27-MAR-2014

APHIS FORM 7023A
AUG 2013

According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0579-0036. The time required to complete this information collection is estimated to average 2 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

OMB APPROVED
0579-0036
Exp.: 10/31/2018

This report is required by law (7 U.S.C. 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

Interagency Report Control
No. 0180-DOA-AN

Fiscal Year 2013

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. REGISTRATION NUMBER
85-R-0003

2. HEADQUARTERS RESEARCH FACILITY *(Name, address, and telephone number as registered with USDA, include ZIP Code)*

LOVELACE RESPIRATORY RESEARCH INSTITUTE
2425 RIDGECREST S E

ALBUQUERQUE, NM 87108

3. REPORTING FACILITY *(List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets, if necessary.)*

FACILITY LOCATIONS *(Sites)*

(b)(7)(F)

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY *(Attach additional sheets, if necessary, or use APHIS FORM 7023A.)*

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. *(An explanation of the procedures producing pain or distress on these animals and the reasons such drugs were not used must be attached to this report.)*	F. TOTAL NUMBER OF ANIMALS **(Cols. C + D + E)**
4. Dogs	19	98	177	12	287
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	63	32	209	304
7. Hamsters	0	0	0	0	0
8. Rabbits	0	5	0	0	5
9. Non-human Primates	116	67	256	227	550
10. Sheep	0	0	0	0	0
11. Pigs	0	3	20	47	70
12. Other Farm Animals					
13. Other Animals	0	5	19	133	157

ASSURANCE STATEMENTS

1.) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.

2.) Each principal investigator has considered alternatives to painful procedures.

3.) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). **A summary of all such exceptions is attached to this annual report.** In addition to identifying the IACUC approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.

4.) The attending veterinarian for this research facility has appropriate authority to ensure the provisions of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL

(*Chief Executive Officer (C.E.O.) or Legally Responsible Institutional Official (I.O.)*)

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

SIGNATURE OF C.E.O. OR I.O.

NAME AND TITLE OF C.E.O. OR I.O. ***(Type or Print)***

DATE SIGNED

(b)(6), (b)(7)(c)

APHIS FORM 7023
JUL 2013

According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0579-0036. The time required to complete this information collection is estimated to average 2 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.	**OMB APPROVED** 0579-0036 **Exp.:** 10/31/2018
This report is required by law (7 U.S.C. 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150. Interagency Report Control No. 0180-DOA-AN	Fiscal Year 2013

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. REGISTRATION NUMBER
85-R-0009

2. HEADQUARTERS RESEARCH FACILITY *(Name, address, and telephone number as registered with USDA, include ZIP Code)*

NEW MEXICO STATE UNIVERSITY
P. O. BOX 30001 BOX 3 RES
OFFICE OF THE VICE PRESIDENT FOR RESEARCH
LAS CRUCES, NM 88003

3. REPORTING FACILITY *(List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets, if necessary.)*

FACILITY LOCATIONS *(Sites)*

(b)(7)(F) [redacted]

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY *(Attach additional sheets, if necessary, or use APHIS FORM 7023A.)*

A. Animals Covered By The Animal Welfare Regulations	**B.** Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	**C.** Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	**D.** Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	**E.** Number of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. *(An explanation of the procedures producing pain or distress on these animals and the reasons such drugs were not used must be attached to this report.)*	**F.** TOTAL NUMBER OF ANIMALS **(Cols. C + D + E)**
4. Dogs	0	0	0	0	0
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	0	0	0	0
7. Hamsters	0	0	0	0	0
8. Rabbits	0	0	0	0	0
9. Non-human Primates	0	0	0	0	0
10. Sheep	0	0	0	0	0
11. Pigs	0	0	0	0	0
12. Other Farm Animals					
13. Other Animals					

ASSURANCE STATEMENTS

1.) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.

2.) Each principal investigator has considered alternatives to painful procedures.

3.) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). **A summary of all such exceptions is attached to this annual report.** In addition to identifying the IACUC approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.

4.) The attending veterinarian for this research facility has appropriate authority to ensure the provisions of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL

(*Chief Executive Officer (C.E.O.) or Legally Responsible Institutional Official (I.O.)*)

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

SIGNATURE OF C.E.O. OR I.O.	NAME AND TITLE OF C.E.O. OR I.O. *(Type or Print)*	DATE SIGNED
(b)(6), (b)(7)(c) [redacted]		03-DEC-2013

JUL 2013

According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0579-0036. The time required to complete this information collection is estimated to average 2 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

OMB APPROVED
0579-0036
Exp.: 10/31/2018

This report is required by law (7 U.S.C. 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

Interagency Report Control No. 0180-DOA-AN

Fiscal Year 2013

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. REGISTRATION NUMBER
85-R-0014

2. HEADQUARTERS RESEARCH FACILITY *(Name, address, and telephone number as registered with USDA, include ZIP Code)*

UNIVERSITY OF NEW MEXICO HEALTH SCIENCES CENTER
Office of A C Compliance 1 Univ of N M
Health Science Center, BRF G37 H, MSC 08 4560
ALBUQUERQUE, NM 87131

3. REPORTING FACILITY *(List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets, if necessary.)*

FACILITY LOCATIONS *(Sites)*

(b)(7)(F)

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY *(Attach additional sheets, if necessary, or use APHIS FORM 7023A.)*

A. Animals Covered By The Animal Welfare Regulations	**B.** Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	**C.** Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	**D.** Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	**E.** Number of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. *(An explanation of the procedures producing pain or distress on these animals and the reasons such drugs were not used must be attached to this report.)*	**F.** TOTAL NUMBER OF ANIMALS **(Cols. C + D + E)**
4. Dogs	0	0	0	0	0
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	0	0	0	0
7. Hamsters	0	0	0	0	0
8. Rabbits	0	0	0	0	0
9. Non-human Primates	0	0	0	0	0
10. Sheep	0	0	0	0	0
11. Pigs	0	0	0	0	0
12. Other Farm Animals					
13. Other Animals					

ASSURANCE STATEMENTS

1.) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.

2.) Each principal investigator has considered alternatives to painful procedures.

3.) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). **A summary of all such exceptions is attached to this annual report.** In addition to identifying the IACUC approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.

4.) The attending veterinarian for this research facility has appropriate authority to ensure the provisions of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL

(*Chief Executive Officer (C.E.O.) or Legally Responsible Institutional Official (I.O.)*)

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

SIGNATURE OF C.E.O. OR I.O.	NAME AND TITLE OF C.E.O. OR I.O. *(Type or Print)*	DATE SIGNED
(b)(6), (b)(7)(c)		03-DEC-2013

According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0579-0036. The time required to complete this information collection is estimated to average 2 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.	**OMB APPROVED** 0579-0036 **Exp.:** 10/31/2018

This report is required by law (7 U.S.C. 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.	Interagency Report Control No. 0180-DOA-AN	Fiscal Year 2013

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. REGISTRATION NUMBER
85-R-0015

2. HEADQUARTERS RESEARCH FACILITY *(Name, address, and telephone number as registered with USDA, include ZIP Code)*

SOUTHWEST BIO-LABS INC.
401 N. 17TH ST., #11

LAS CRUCES, NM 88005

3. REPORTING FACILITY *(List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets, if necessary.)*

FACILITY LOCATIONS *(Sites)*

(b)(7)(F)

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY *(Attach additional sheets, if necessary, or use APHIS FORM 7023A.)*

A. Animals Covered By The Animal Welfare Regulations	**B.** Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	**C.** Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	**D.** Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	**E.** Number of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. *(An explanation of the procedures producing pain or distress on these animals and the reasons such drugs were not used must be attached to this report.)*	**F.** TOTAL NUMBER OF ANIMALS **(Cols. C + D + E)**
4. Dogs	0	9	51	0	60
5. Cats	7	31	0	0	31
6. Guinea Pigs	0	0	0	0	0
7. Hamsters	0	0	0	0	0
8. Rabbits	0	0	0	0	0
9. Non-human Primates	0	0	0	0	0
10. Sheep	0	0	0	0	0
11. Pigs	0	0	0	0	0
12. Other Farm Animals					
13. Other Animals					

ASSURANCE STATEMENTS

1.) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.

2.) Each principal investigator has considered alternatives to painful procedures.

3.) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). **A summary of all such exceptions is attached to this annual report.** In addition to identifying the IACUC approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.

4.) The attending veterinarian for this research facility has appropriate authority to ensure the provisions of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL

(*Chief Executive Officer (C.E.O.) or Legally Responsible Institutional Official (I.O.)*)

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

SIGNATURE OF C.E.O. OR I.O.	**NAME AND TITLE OF C.E.O. OR I.O.** *(Type or Print)*	**DATE SIGNED**
(b)(6), (b)(7)(c)		04-DEC-2013

According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0579-0036. The time required to complete this information collection is estimated to average 2 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

OMB APPROVED
0579-0036
Exp.: 10/31/2018

This report is required by law (7 U.S.C. 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

Interagency Report Control No. 0180-DOA-AN

Fiscal Year 2013

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. REGISTRATION NUMBER
85-R-0019

2. HEADQUARTERS RESEARCH FACILITY *(Name, address, and telephone number as registered with USDA, include ZIP Code)*

RAISED BY WOLVES INC.
HC 62 BOX 3127

THOREAU, NM 87323

3. REPORTING FACILITY *(List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets, if necessary.)*

FACILITY LOCATIONS *(Sites)*

(b)(7)(F)

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY *(Attach additional sheets, if necessary, or use APHIS FORM 7023A.)*

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. *(An explanation of the procedures producing pain or distress on these animals and the reasons such drugs were not used must be attached to this report.)*	F. TOTAL NUMBER OF ANIMALS **(Cols. C + D + E)**
4. Dogs	0	7	0	0	7
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	0	0	0	0
7. Hamsters	0	0	0	0	0
8. Rabbits	0	0	0	0	0
9. Non-human Primates	0	0	0	0	0
10. Sheep	0	0	0	0	0
11. Pigs	0	0	0	0	0
12. Other Farm Animals					
13. Other Animals					

ASSURANCE STATEMENTS

1.) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.

2.) Each principal investigator has considered alternatives to painful procedures.

3.) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). **A summary of all such exceptions is attached to this annual report.** In addition to identifying the IACUC approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.

4.) The attending veterinarian for this research facility has appropriate authority to ensure the provisions of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL

(*Chief Executive Officer (C.E.O.) or Legally Responsible Institutional Official (I.O.)*)

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

SIGNATURE OF C.E.O. OR I.O.

NAME AND TITLE OF C.E.O. OR I.O. ***(Type or Print)***

(b)(6), (b)(7)(c)

DATE SIGNED
31-OCT-2013

According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0579-0036. The time required to complete this information collection is estimated to average 2 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

OMB APPROVED
0579-0036
Exp.: 10/31/2018

This report is required by law (7 U.S.C. 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

Interagency Report Control No. 0180-DOA-AN

Fiscal Year 2013

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. REGISTRATION NUMBER
85-R-0025

2. HEADQUARTERS RESEARCH FACILITY *(Name, address, and telephone number as registered with USDA, include ZIP Code)*

Brown Mackie College -Albuquerque
10500 Copper Avenue N E

ALBUQUERQUE, NM 87123

3. REPORTING FACILITY *(List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets, if necessary.)*

FACILITY LOCATIONS *(Sites)*

(b)(7)(F)

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY *(Attach additional sheets, if necessary, or use APHIS FORM 7023A.)*

A. Animals Covered By The Animal Welfare Regulations	**B.** Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	**C.** Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	**D.** Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	**E.** Number of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. *(An explanation of the procedures producing pain or distress on these animals and the reasons such drugs were not used must be attached to this report.)*	**F.** TOTAL NUMBER OF ANIMALS **(Cols. C + D + E)**
4. Dogs	0	0	0	0	0
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	0	0	0	0
7. Hamsters	0	0	0	0	0
8. Rabbits	0	0	0	0	0
9. Non-human Primates	0	0	0	0	0
10. Sheep	0	0	0	0	0
11. Pigs	0	0	0	0	0
12. Other Farm Animals					
13. Other Animals					

ASSURANCE STATEMENTS

1.) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.

2.) Each principal investigator has considered alternatives to painful procedures.

3.) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). **A summary of all such exceptions is attached to this annual report.** In addition to identifying the IACUC approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.

4.) The attending veterinarian for this research facility has appropriate authority to ensure the provisions of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL

(*Chief Executive Officer (C.E.O.) or Legally Responsible Institutional Official (I.O.)*)

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

SIGNATURE OF C.E.O. OR I.O.	**NAME AND TITLE OF C.E.O. OR I.O.** *(Type or Print)*	**DATE SIGNED**
(b)(6), (b)(7)(c)		

APHIS FORM 7023
JUL 2013

According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0579-0036. The time required to complete this information collection is estimated to average 2 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

OMB APPROVED
0579-0036
Exp.: 10/31/2018

This report is required by law (7 U.S.C. 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

Interagency Report Control No. 0180-DOA-AN

Fiscal Year 2013

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. REGISTRATION NUMBER
85-R-0026

2. HEADQUARTERS RESEARCH FACILITY *(Name, address, and telephone number as registered with USDA, include ZIP Code)*

Eastern New Mexico University- Roswell
P.O. Box 6000

ROSWELL, NM 88202

3. REPORTING FACILITY *(List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets, if necessary.)*

FACILITY LOCATIONS *(Sites)*

(b)(7)(F) [redacted]

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY *(Attach additional sheets, if necessary, or use APHIS FORM 7023A.)*

A. Animals Covered By The Animal Welfare Regulations	**B.** Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	**C.** Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	**D.** Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	**E.** Number of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. *(An explanation of the procedures producing pain or distress on these animals and the reasons such drugs were not used must be attached to this report.)*	**F.** TOTAL NUMBER OF ANIMALS **(Cols. C + D + E)**
4. Dogs	0	0	0	0	0
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	0	0	0	0
7. Hamsters	0	0	0	0	0
8. Rabbits	0	0	0	0	0
9. Non-human Primates	0	0	0	0	0
10. Sheep	0	0	0	0	0
11. Pigs	0	0	0	0	0
12. Other Farm Animals					
13. Other Animals					

ASSURANCE STATEMENTS

1.) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.

2.) Each principal investigator has considered alternatives to painful procedures.

3.) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). **A summary of all such exceptions is attached to this annual report.** In addition to identifying the IACUC approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.

4.) The attending veterinarian for this research facility has appropriate authority to ensure the provisions of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL

(*Chief Executive Officer (C.E.O.) or Legally Responsible Institutional Official (I.O.)*)

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

SIGNATURE OF C.E.O. OR I.O.	**NAME AND TITLE OF C.E.O. OR I.O.** *(Type or Print)*	**DATE SIGNED**
(b)(6), (b)(7)(c) [redacted]		

APHIS FORM 7023
JUL 2013

According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0579-0036. The time required to complete this information collection is estimated to average 2 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.	**OMB APPROVED** 0579-0036 **Exp.:** 10/31/2018
This report is required by law (7 U.S.C. 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150. Interagency Report Control No. 0180-DOA-AN	Fiscal Year 2013

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. REGISTRATION NUMBER
85-V-0001

2. HEADQUARTERS RESEARCH FACILITY *(Name, address, and telephone number as registered with USDA, include ZIP Code)*

V A MEDICAL CENTER #501
1501 SAN PEDRO DRIVE SE
Building 10, VA Medical Center # 501
ALBUQUERQUE, NM 87108

3. REPORTING FACILITY *(List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets, if necessary.)*

FACILITY LOCATIONS *(Sites)*

(b)(7)(F) [redacted]

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY *(Attach additional sheets, if necessary, or use APHIS FORM 7023A.)*

A. Animals Covered By The Animal Welfare Regulations	**B.** Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	**C.** Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	**D.** Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	**E.** Number of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. *(An explanation of the procedures producing pain or distress on these animals and the reasons such drugs were not used must be attached to this report.)*	**F.** TOTAL NUMBER OF ANIMALS **(Cols. C + D + E)**
4. Dogs	0	0	0	0	0
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	0	0	0	0
7. Hamsters	0	0	0	0	0
8. Rabbits	0	0	66	0	66
9. Non-human Primates	0	0	0	0	0
10. Sheep	0	0	0	0	0
11. Pigs	0	0	0	0	0
12. Other Farm Animals					
13. Other Animals					

ASSURANCE STATEMENTS

1.) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.

2.) Each principal investigator has considered alternatives to painful procedures.

3.) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). **A summary of all such exceptions is attached to this annual report.** In addition to identifying the IACUC approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.

4.) The attending veterinarian for this research facility has appropriate authority to ensure the provisions of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL

(*Chief Executive Officer (C.E.O.) or Legally Responsible Institutional Official (I.O.)*)

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

SIGNATURE OF C.E.O. OR I.O.	NAME AND TITLE OF C.E.O. OR I.O. *(Type or Print)*	DATE SIGNED
(b)(6), (b)(7)(c) [redacted]	[redacted]	03-DEC-2013

Certificate No: 85-R-0003

Category E Explanations

This institute had 19 studies that included USDA covered species in Category E during the reporting period of 01 October 2012 through 30 September 2013.

Study 1: 82 Guinea Pigs *(Cavia porcellus)*

This study is classified as a Category E. This is an LD50 research study to demonstrate expected disease of a chemical agent and is required to properly evaluate therapeutics. Administration of analgesics to alleviate pain cannot be used because they can interfere with the progression of the chemical agent responses. This chemical warfare agent may be deployed in either a civilian or military setting. The toxic effects of the agent depend on the level of exposure. Large amounts of this chemical agent can lead to convulsions, paralysis, and loss of respiratory function which will ultimately result in death. There is a need to develop therapeutic countermeasures to counteract the toxic effects of this chemical agent. Once an LD50 has been established, a sub-LD50 dose will be administered and a pharmacokinetics profile will be determined. LD50 studies and exposures are necessary to properly evaluate the patient's response to therapeutics following exposure to this chemical agent. It is essential these therapeutic measures be verified in order to improve survivability in exposed military personnel and civilians. A terrorist attack is likely to expose the victims (center of exposure) to 1-3 LD50 of this chemical agent. Therefore animals are to be exposed to these doses to ascertain the efficacy of any potential therapeutic measure. Unfortunately, these doses will produce significant disease; however, the research focuses on developing countermeasures to reduce this mortality. Animals are observed for a minimum of the first 4 hours post exposure; if moribund criteria are observed the animal is immediately anesthetized prior to being humanely euthanized to minimize pain and distress. After the level of mortality associated with these doses of chemical agent are established, countermeasures will be tested in subsequent protocols. It is inhumane to conduct therapeutic efficacy studies on humans with nerve agents or any agent that may result in death. It is also impossible to conduct these studies in-vitro as the resulting injury from this chemical agent is more complex than can be simulated in a petri dish.

Study 2: 30 Ferrets *(Mustela putorius furo)*

This study is classified as a Category E. The ferret model is selected for its similarities to human infection and the pathogenicity of this infectious disease. There may be discomfort caused by the infection and concomitant inflammatory response, but no analgesics will be used as they may abrogate the inflammatory response to infection. The use of analgesics could alter the pathogenesis and immunologic response to infection, thus making it impossible to interpret the data obtained in this study. Narcotic analgesics were shown to interfere with the mechanism(s) responsible for interferon production (Geher, W.F. et al, J. Toxicol Environ Health 2:577-582, 1977; Hung, C.Y. et al Proc Soc Exp Biol Med 142:106-111, 1973.) Moreover, opioids can suppress natural killer cell activity (Beilin, B., et al., Brain Behav Immun 3: 129-137, 1989). Also, analgesics including buprenorphine can cause histamine release (Marone, G., et al Int Arch Allergy Immunol 124: 249-252, 2001: Stellato, C. and Marone, G., Chem Immunol 62: 108-131, 195) and respiratory depression (Soma, L.R., Ann NY Acad Sci 406: 32-47, 1995). Histamine is a well-known inflammatory mediator and plays a central role in the pathogenesis of allergic and inflammatory disease by modulating vascular and airway responses. Histamine has been shown to induce activation of macrophages (Mozooni, A., et al, J Immunol 170: 2269-2273, 1999), inhibit interferon alpha release from dendritic cells (Marone, G., et al., Int Arch Allergy Immunol, 124: 249-252, 2001) and increase the synthesis and release of IL-10 from macrophages (Sirois, J., et al., J. Immunol 164: 2964-2970, 200). Clearly, the analgesic induced release of histamine would directly interfere with the inflammatory process. Studies by Piersman el al, (Lab Anim 33: 328-333, 1999) provide an additional example of how analgesics may modify the expression the disease process. These investigators, using an established murine model of endotoxemia, showed that the opioids, fentanyl and buprenorphine, directly altered the outcome of their experiments by modulating the immune response. In this case, both opioids caused significant decreases in circulating levels of tumor necrosis factor alpha following administration of lipopolysaccharide.

Ferrets may exhibit anorexia and weight loss, dyspnea, diarrhea, or neurological signs. If the ferrets exhibit clinical signs indicating they will not survive until the next observation period, they will be humanely euthanized.

Study 3: 36 Ferrets *(Mustela putorius furo)*

This study is classified as Category E. The ferret model is selected for its similarities to human infection and the pathogenicity of this infectious disease.

Animals being challenged with this infectious disease are expected to experience illness related symptoms such as fever, gastrointestinal and neurological disorders, anorexia, and dehydration, hematological and clinical chemistry changes, ultimately ending in humane euthanasia prior to death. Animals being used to optimize the aerosol delivery system are not expected to experience pain or discomfort. Illness experienced by challenged animals must not be treated with analgesics, as this would compromise the scientific integrity of the study, mask the pathogenesis of the disease, obscure secondary efficacy parameters such has amelioration of clinical signs, could inadvertently accelerate the disease process, and confound the interpretation of euthanasia criteria. Importantly, the use of analgesics could alter the pathogenesis and immunologic response to infection, thus making it impossible to interpret the data obtained in this study. Narcotic analgesics were shown to interfere with the mechanism(s) responsible for interferon production (Geher, W.F. et al., J. Toxicol Environ Health 2:577-582, 1977; Hugh, C.Y. et al. Proc Soc Exp Diol Med 142:106-111, 1973). Moreover opioids can suppress Natural Killer (NK) cell activity (Beilin, B., et al. Brain Behav Immun 3:129-137, 1989). Also analgesics including buprenorphine can cause histamine release (Marone, G., et al. Int Arch Allergy Immunol 124:249-252, 2001; Stellato, C., Ann NY Acad Sci 406:32-47, 1995). Histamine is a well-known inflammatory mediator and plays a central role in the pathogenesis of allergic and inflammatory diseases by modulating vascular and airway response. Histamine has been shown to induce activation of human macrophages (Mozzoni, A., et al. J Immunol 170:269-2273, 1999), inhibit interferon alpha release from dendritic cells (Marone, G., et al., Int Arch Allergy Immunol, 124:249-252, 2001) and increase the synthesis and release of IL-10 from human macrophages (Sirois, J., et al. J. Immunol 164:2964-2970, 2000). Clearly, the analgesic-induced release of histamine would directly interfere with the inflammatory process. Studies by Piersman et al, (Lab Anim 33:328-333, 1999) provide an additional example of how analgesics may modify the expression of the disease process. These investigators, using an established murine model of endotoxemia, which showed that the opioids, fentanyl and buprenorphine, directly altered the outcome of their experiments by modulating the immune response. In this case, both opioids caused significant decreases in circulating levels of tumor necrosis factor alpha following administration of lipopolysaccharide (LPS).

If the ferrets exhibit clinical signs indicating they will not survive until the next observation period, they will be humanely euthanized. This study is being conducted under the Animal Rule which allows for testing therapeutics in animals when tests cannot ethically be tested in humans and field efficacies tests are not feasible. The pathogenesis of this infection is complex, involving a number of cell types and organs, and the assessment of efficacy is often measured by survival and reduction of clinical signs/symptoms. Therefore, in vitro techniques are insufficient to measure efficacy. Furthermore, for therapeutics aimed at licensure for the use of prophylactics against human disease, the path to FDA approval is unique. Controlled studies of clinical effectiveness in humans are impossible, since large groups of people are not typically exposed to these diseases. Instead of relying on human studies, the Animal Rule allows the FDA to approve drugs that are shown to be effective in two animal models, without clinical trials for effectiveness, under the following conditions:

-Human efficacy trials are not feasible or ethical
-Efficacy is shown in well understood animal models
-Efficacy is substantiated in multiple species
-Human clinical data on safety, toxicity and immunogenicity is still required

Study 4: 45 Guinea Pigs *(Cavia porcellus)*

This study is classified as a Category E. This is an LD50 research study to demonstrate expected disease of a nerve agent and is required to properly evaluate therapeutics. No analgesics will be administered to these animals as administration may interfere with the survivability of the animals. Placing animals in an altered state of conciseness would lead to an unpredictable LD50. This chemical warfare agent may be deployed in either a civilian or military setting. The toxic effects of the agent depend on the level of exposure. Large amounts of this nerve agent can lead to convulsions, paralysis, and loss of respiratory function which will ultimately result in death. There is a need to develop therapeutic countermeasures to counteract the toxic effects of this chemical agent. LD50 studies and exposures are necessary to properly evaluate the patient's response to therapeutics following exposure to this chemical agent. It is essential these therapeutic measures be verified in order to improve survivability in exposed military personnel and civilians. A terrorist attack is likely to expose the victims (center of exposure) to 1-3 LD50 of this chemical agent. Therefore animals are to be exposed to these doses to ascertain the efficacy of any potential therapeutic measure. Unfortunately, these doses will produce significant disease; however, the research focuses on developing countermeasures to reduce this mortality. Animals are observed for a minimum of the first 6 hours post exposure; if moribund criteria is observed the animal is immediately anesthetized prior to being humanely euthanized to minimize pain and distress. After the level of mortality associated with these doses of chemical agent are established, countermeasures will be tested in subsequent protocols. It is inhumane to conduct therapeutic efficacy studies on humans with nerve agents or any agent that may result in death. It is also impossible to conduct these studies in-vitro as the resulting injury from this chemical agent is more complex than can be simulated in a petri dish. If the animals exhibit clinical signs indicating they will not survive until the next observation period, they will be humanely euthanized.

Study 5: 47 Gottingen Mini Pigs *(Sus scrofa domesticus)*

This study is classified as a Category E. The illness experienced by animals exposed to radiation must not be treated with analgesics because that treatment might interfere with h-ARS pathogenesis. However NSAIDs, anti-emetics, and antidiarrheal agents will be administered per the veterinary staff as part of the development of the supportive care protocol for this model. Minimal supportive care will be provided in order to model the disease that would occur in a mass casualty situation in which the quality of supportive care may be dictated by the volume of supplies and availability of qualified personnel; for example only over the counter drugs may be available rather than the full complement of care that can be provided to an individual in a hospital after a single radiation exposure incident. The use of additional analgesics not listed in the study design could alter the pathogenesis and immunologic response to irradiation, altering the data interpretation. For the purposes of this study, offering excessive pain or stress relieving agents is contraindicated because we need to study the natural progression of the disease process. The confounding influence of other drugs could adversely affect the lethal dose establishment and invalidate the study.

Study 6: 24 Ferrets *(Mustela putorius furo)*

This study is classified Category E. The ferret model is selected for its similarities to human infection and the pathogenicity of this infectious disease.

The goal of this protocol is to test the safety of these viruses in regards to their predicted lack of replication efficiency versus a known infectious virus of the same type. Animals being challenged with this infectious disease are expected to experience illness related symptoms such as fever, gastrointestinal and neurological disorders, anorexia and dehydration, hematological and clinical chemistry changes, ultimately ending in humane euthanasia prior to death. Illness experienced by challenged animals must not be treated with analgesics, as this would compromise the scientific integrity of the study, mask the pathogenesis of the disease, obscure secondary efficacy parameters such as amelioration of clinical signs, could inadvertently accelerate the disease process, and confound the interpretation of euthanasia criteria. Importantly, the use of analgesics could alter the pathogenesis and immunologic response to infection, thus making it impossible to interpret the data obtained in this study. Narcotic analgesics were shown to interfere with the mechanism(s) responsible for interferon production (Geher, W.F. et al., J. Toxicol Environ Health 2:577-582, 1977; Hugh, C.Y. et al. Proc Soc Exp Diol Med 142:106-111, 1973). Moreover opioids can suppress Natural Killer (NK) cell activity (Beilin, B., et al. Brain Behav Immun 3:129-137, 1989). Also analgesics including buprenorphine can cause histamine release (Marone, G., et al. Int Arch Allergy Immunol 124:249-252, 2001; Stellato, C., Ann NY Acad Sci 406:32-47, 1995). Histamine is a well-known inflammatory mediator and plays a central role in the pathogenesis of allergic and inflammatory diseases by modulating vascular and airway response. Histamine has been shown to induce activation of human macrophages (Mozzoni, A., et al. J Immunol 170:269-2273, 1999), inhibit interferon alpha release from dendritic cells (Marone, G., et al., Int Arch Allergy Immunol, 124:249-252, 2001) and increase the synthesis and release of IL-10 from human macrophages (Sirois, J., et al. J. Immunol 164:2964-2970, 2000). Clearly, the analgesic-induced release of histamine would directly interfere with the inflammatory process. Studies by Piersman et al, (Lab Anim 33:328-333, 1999) provide an additional example of how analgesics may modify the expression of the disease process. These investigators, using an established murine model of endotoxemia, which showed that the opioids, fentanyl and buprenorphine, directly altered the outcome of their experiments by modulating the immune response. In this case, both opioids caused significant decreases in circulating levels of tumor necrosis factor alpha following administration of lipopolysaccharide (LPS).

If the ferrets exhibit clinical signs indicating they will not survive until the next observation period, they will be humanely euthanized. This study is being conducted under the Animal Rule which allows for testing therapeutics in animals when tests cannot ethically be tested in humans and field efficacies tests are not feasible.

The pathogenesis of this infection is complex, involving a number of cell types and organs, and the assessment of efficacy is often measured by survival and reduction of clinical signs/symptoms. Therefore, in vitro techniques are insufficient to measure efficacy. Furthermore, for therapeutics aimed at licensure for the use of prophylactics against human disease, the path to FDA approval is unique. Controlled studies of clinical effectiveness in humans are impossible, since large groups of people are not typically exposed to these diseases. Instead of relying on human studies, the Animal Rule allows the FDA to approve drugs that are shown to be effective in two animal models, without clinical trials for effectiveness, under the following conditions:

-Human efficacy trials are not feasible or ethical

-Efficacy is shown in well understood animal models

-Efficacy is substantiated in multiple species

-Human clinical data on safety, toxicity and immunogenicity is still required

Therefore, the use of animals is a necessary means to support efficacy in therapeutics aimed at preventing human disease from many bioterrorism agents and lethal emerging infectious diseases. Furthermore, optimization of the ferret inhalation exposure is needed, as there are no known artificial replicas of the ferret lung.

Study 7: 9 Nonhuman Primates *(Chlorocebus aethiops)*
This study is classified as a Category E. It will look at the efficacy of the antibiotic in an animal model of infectious disease. This study will support future submissions to the FDA under the "Animal Efficacy Rule" amendment (21 CFR Parts 314 subpart I and 601 subpart H) to FDA's new drug and biological products regulations. The "Animal Efficacy Rule" applies when adequate and well controlled clinical studies in humans cannot be ethically conducted and field efficacy studies in humans are not feasible. The animal endpoints must clearly relate to the desired benefit in humans, generally the enhancement of survival or prevention of major morbidity. Therefore, it is necessary to challenge the animals with the pathogen and follow the disease process. The giving of pain or stress relieving agents is contraindicated because it may interfere in determining the efficacy of the therapeutic. Furthermore, we need to study the natural progression of the disease process in the absence and presence of the therapeutic agent without the confounding influence of another agent on the pathophysiological process of animal infection. The illness experienced by animals exposed to the infectious agent must not be treated with analgesics because treatment will interfere with studying the pathogenesis of the disease. The symptoms of this illness may include decrease in body temperature, respiratory distress, cyanosis of the mucous membranes, seizures, unresponsiveness to stimuli, reduced appetite, and weakness.

Importantly, the use of analgesics could alter the pathogenesis and immunologic response to infection, thus making it impossible to interpret the data obtained in this study. It is likely the use of analgesics will interfere with the accurate measurements of the disease process or with the antibiotic treatment whose efficacy is being assessed. Narcotic analgesics were shown to interfere with the mechanism(s) responsible for interferon production (Geher, W.F. et al., J. Toxicol Environ Health 2:577-582, 1977;

Hung, C. Y. et. al. Proc Soc Exp Biol Med 142:106-111-1973). Moreover opioids can suppress Natural Killer (NK) cell activity (Beilin, B., et al., Brain Behav Immun 3: 129-137, 1989). Also, analgesics including buprenorphine can cause histamine release (Marone, G., et al Int Arch Allergy Immunol 124:249-252, 2001; Stellato, C., and Marone, G., Chem Immunol 62: 108-131, 1995) and respiratory depression (Soma, L.R., Ann NY Acad Sci 406: 32-47, 1995). Histamine is a well-known inflammatory mediator and plays a central role in the pathogenesis of allergic and inflammatory diseases by modulating vascular and airway responses. Histamine has been shown to induce activation of human macrophages (Mozzoni, A., et al, J Immunol 170: 2269-2273, 1999), inhibit interferon alpha release from dendritic cells (Marone, G., et al., Int Arch Allergy Immunol, 124, 249-252, 2001) and increase the synthesis and release of IL-10 form human macrophages (Sirois, J., et al, J. Immunol 164:2964-2970, 2000). Clearly, the analgesic-induced release of histamine would directly interfere with the inflammatory process. Studies by Piersman et al, (Lab Anim 33: 328-333, 1999) provide an additional example of how analgesics may modify the expression of the disease process. These investigators, using an established murine model of endotoxemia, showed that the opioids, fentanyl and buprenorphine, directly altered the outcome of their experiments by modulating the immune response. In this case, both opioids caused significant decreases in circulating levels of tumor necrosis factor alpha following administration of lipopolysaccharide (LPS).

Study 8: 6 Nonhuman Primates (*Macaca mulatta)*

This study is classified as Category E. Exposure to ionizing radiation causes Hematopoietic Acute Radiation Syndrome (ARS). Clinical symptoms are unavoidable. The illness experienced by animals exposed to radiation must not be treated with analgesics because that treatment might interfere with ARS pathogenesis. However opioids, anti-emetics, and anti-diarrheals will be administered per the veterinary staff as part of the development of the supportive care protocol previously utilized by expert collaborators. Minimal supportive care will be provided in order to model the lethality that would occur in a mass casualty situation in which the quality of supportive care may be dictated by the volume of supplies and availability of qualified personnel; for example only over the counter drugs may be available rather than the full complement of care (including blood support) that can be provided to an individual in a hospital after a single radiation exposure incident. Although the goal of this study is not to model the entire lethality curve, the study treatments should remain the same so the results of this study can be utilized for the full development project to minimize unnecessary duplication of work. The use of additional analgesics not listed in the study design could alter the pathogenesis and immunologic response to irradiation, altering the data interpretation. For the purposes of developing general models of irradiation, offering excessive pain or stress relieving agents is contraindicated because we need to study the natural progression of the disease process. The confounding influence of other drugs could adversely affect the lethal dose establishment and invalidate the study.

Acute radiation syndrome is not specific to a single organ or system therefore currently there are no in silica or in vitro models that can accurately reflect the possible synergistic or interactive responses. In vitro and in silica models are useful to perform investigative or mechanistic work once the primary system or organ is verified however these initial studies are crucial for understanding the effects of the syndrome.

Study 9: 6 Nonhuman Primates *(Macaca mulatta)*

This study is classified as Category E. This study will support a package to the FDA for the Animal Efficacy Rule which allows for testing therapeutics in animals when therapeutics cannot be ethically tested in humans. A need to identify and develop mitigating agents that can be used to treat the civilian population after a radiological event has emerged. A model of acute radiation syndrome (ARS) associated with high doses of total body irradiation has been developed in NHPs. Efficacy studies to optimize treatments for ARS can now be conducted using this model. Exposure to ionizing radiation causes Hematopoietic Acute Radiation Syndrome. Clinical symptoms are unavoidable. The illness experienced by animals exposed to radiation must not be treated with analgesics because that treatment might interfere with ARS pathogenesis. However opioids, anti-emetics, and anti-diarrheals will be administered per the veterinary staff as part of the development of the supportive care protocol previously utilized by expert collaborators. Minimal supportive care will be provided in order to model the lethality that would occur in a mass casualty situation in which the quality of supportive care may be dictated by the volume of supplies and availability of qualified personnel; for example only over the counter drugs may be available rather than the full complement of care (including blood support) that can be provided to an individual in a hospital after a single radiation exposure incident. Although the goal of this study is not to model the entire lethality curve, the study treatments should remain the same so the results of this study can be utilized for the full development project to minimize unnecessary duplication of work. The use of additional analgesics not listed in the study design could alter the pathogenesis and immunologic response to irradiation, altering the data interpretation. For the purposes of developing general models of irradiation, offering excessive pain or stress relieving agents is contraindicated because we need to study the natural progression and lethality of the disease process. The confounding influence of other drugs could adversely affect the lethal dose establishment and invalidate the study.

Acute radiation syndrome is not specific to a single organ or system therefore currently there are no in silica or in vitro models that can accurately reflect the possible synergistic or interactive responses. In vitro and in silica models are useful to perform investigative or mechanistic work once the primary system or organ is verified however these initial studies are crucial for understanding the effects of the syndrome.

Study 10: 20 Nonhuman Primates *(Macaca fascicularis)*

This study is classified as category E. Development of medicines against biological threats is a priority for the U.S. government. As it is not ethical to test the ability of these medicines to help prevent or cure disease in human clinical trials, we must test them in well-controlled animal studies. The NHP model of inhalational of biological agents has been used to study vaccines and therapeutics. This study aims to demonstrate whether administration of a therapeutic will reduce or prevent death due to a lethal aerosol dose of a virulent pathogen. Signs of illness may include elevated body temperature, loss of appetite, weight loss, weakness, lethargy and lack of grooming. Illness experienced by challenged animals must not be treated with analgesics, as this would comprise the scientific integrity of the study, mask the pathogenesis of the disease (and obscure secondary efficacy parameters, such as amelioration of clinical signs), could inadvertently accelerate the disease process (additive effect to the infection), and confound the interpretation of euthanasia criteria. Importantly, the use of analgesics could alter the pathogenesis and immunologic response to infection, thus making it impossible to interpret the data obtained in this study. Narcotic analgesics were shown to interfere with the mechanism(s) responsible for interferon production (Geher, W.F. et al., J. Toxicol Environ Health 2:577-582, 1977; Hung, C. Y. et. al. Proc Soc Exp Biol Med 142:106-111-1973). Moreover opioids can suppress Natural Killer (NK) cell activity (Beilin, B., et al., Brain Behav Immun 3: 129-137, 1989). Also, analgesics including buprenorphine can cause histamine release (Marone, G., et al Int Arch Allergy Immunol 124:249-252, 2001; Stellato, C., and Marone, G., Chem Immunol 62: 108-131, 1995) and respiratory depression (Soma, L.R., Ann NY Acad Sci 406: 32-47, 1995). Histamine is a well-known inflammatory mediator and plays a central role in the pathogenesis of allergic and inflammatory diseases by modulating vascular and airway responses. Histamine has been shown to induce activation of human macrophages (Mozzoni, A., et al, J Immunol 170: 2269-2273, 1999), inhibit interferon alpha release from dendritic cells (Marone, G., et al., Int Arch Allergy Immunol, 124, 249-252, 2001) and increase the synthesis and release of IL-10 from human macrophages (Sirois, J., et al, J. Immunol 164:2964-2970, 2000). Clearly, the analgesic-induced release of histamine would directly interfere with the inflammatory process. Studies by Piersman et al, (Lab Anim 33: 328-333, 1999) provide an additional example of how analgesics may modify the expression of the disease process. These investigators, using an established murine model of endotoxemia, showed that the opioids fentanyl and buprenorphine directly altered the outcome of their experiments by modulating the immune response. In this case, both opioids caused significant decreases in circulating levels of tumor necrosis factor alpha following administration of lipopolysaccharide (LPS).

This study is being conducted under the "Animal Rule" (subpart I of 21CFR314 and subpart H of 21CFR601) which allows for testing therapeutics in animals when tests cannot ethically be tested in humans and field efficacies tests are not feasible.

The results from this study may be used to support future submissions to the FDA under the "Animal Rule" amendment (21CFR Parts 314 subpart I and 601 subpart H) to FDA's new drug and biological products regulations. The animal endpoints must clearly relate to the desired benefit in humans, generally the enhancement of survival or prevention of major morbidity. Therefore, it is necessary to challenge the NHP with a dose of agent and follow the disease progression. Any animals found moribund will be humanely euthanized.

Study 11: 70 Nonhuman Primates *(Macaca mulatta)*

This study is classified as Category E. A need to identify and develop mitigating agents that can be used to treat the civilian population after a radiological event has emerged. A model of acute radiation syndrome (ARS) associated with high doses of total body irradiation has been developed in NHPs. Exposure to ionizing radiation causes Hematopoietic Acute Radiation Syndrome. Clinical symptoms are unavoidable. The illness experienced by animals exposed to radiation must not be treated with analgesics because that treatment might interfere with ARS pathogenesis. However opioids, anti-emetics, and anti-diarrheals will be administered per the veterinary staff as part of the development of the supportive care protocol previously utilized by expert collaborators. Minimal supportive care will be provided in order to model the lethality that would occur in a mass casualty situation in which the quality of supportive care may be dictated by the volume of supplies and availability of qualified personnel; for example only over the counter drugs may be available rather than the full complement of care (including blood support) that can be provided to an individual in a hospital after a single radiation exposure incident. Although the goal of this study is not to model the entire lethality curve, the study treatments should remain the same so the results of this study can be utilized for the full development project to minimize unnecessary duplication of work. The use of additional analgesics not listed in the study design could alter the pathogenesis and immunologic response to irradiation, altering the data interpretation. For the purposes of developing general models of irradiation, offering excessive pain or stress relieving agents is contraindicated because we need to study the natural progression of the disease process. The confounding influence of other drugs could adversely affect the lethal dose establishment and invalidate the study. The animals will be humanely euthanized as the method of treatment.

Acute radiation syndrome is not specific to a single organ or system therefore currently there are no in silica or in vitro models that can accurately reflect the possible synergistic or interactive responses. In vitro and in silica models are useful to perform investigative or mechanistic work once the primary system or organ is verified however these initial studies are crucial for understanding the effects of the syndrome.

Study 12: 97 Nonhuman Primates *(Macaca mulatta)*

This study is classified as Category E. A need to identify and develop mitigating agents that can be used to treat the civilian population after a radiological event has emerged. A model of acute radiation syndrome (ARS) associated with high doses of total body irradiation has been developed in NHPs. Exposure to ionizing radiation causes Hematopoietic Acute Radiation Syndrome. Clinical symptoms are unavoidable. The illness experienced by animals exposed to radiation must not be treated with analgesics because that treatment might interfere with ARS pathogenesis. However opioids, anti-emetics, and anti-diarrheals will be administered per the veterinary staff as part of the development of the supportive care protocol previously utilized by expert collaborators. Minimal supportive care will be provided in order to model the lethality that would occur in a mass casualty situation in which the quality of supportive care may be dictated by the volume of supplies and availability of qualified personnel; for example only over the counter drugs may be available rather than the full complement of care (including blood support) that can be provided to an individual in a hospital after a single radiation exposure incident. Although the goal of this study is not to model the entire lethality curve, the study treatments should remain the same so the results of this study can be utilized for the full development project to minimize unnecessary duplication of work. The use of additional analgesics not listed in the study design could alter the pathogenesis and immunologic response to irradiation, altering the data interpretation. For the purposes of developing general models of irradiation, offering excessive pain or stress relieving agents is contraindicated because we need to study the natural progression of the disease process. The confounding influence of other drugs could adversely affect the lethal dose establishment and invalidate the study. The animals will be humanely euthanized as the method of treatment.

Acute radiation syndrome is not specific to a single organ or system therefore currently there are no in silica or in vitro models that can accurately reflect the possible synergistic or interactive responses. In vitro and in silica models are useful to perform investigative or mechanistic work once the primary system or organ is verified however these initial studies are crucial for understanding the effects of the syndrome.

Study 13: 43 Ferrets *(Mustela putorius furo)*

This study is classified Category E. The ferret model is selected for its similarities to human infection and the pathogenicity of this infectious disease. The goal of this protocol is to test the efficacy of these vaccines in regards to the reduction in replication of the challenge virus, which replicates easily in the ferret model. Animals being challenged with this infectious disease are expected to experience illness related symptoms such as weight loss, respiratory distress, lethargy, fever, gastrointestinal and neurological disorders, anorexia, and dehydration, hematological and clinical chemistry changes, ultimately ending in humane euthanasia. Illness experienced by challenged animals must not be treated with analgesics, as this would compromise the scientific integrity of the study, mask the pathogenesis of the disease, obscure secondary efficacy parameters such has amelioration of clinical signs, could inadvertently accelerate the disease process, and confound the interpretation of euthanasia criteria. Importantly, the use of analgesics could alter the pathogenesis and immunologic response to infection, thus making it impossible to interpret the data obtained in this study. Narcotic analgesics were shown to interfere with the mechanism(s) responsible for interferon production (Geher, W.F. et al., J. Toxicol Environ Health 2:577-582, 1977; Hugh, C.Y. et al. Proc Soc Exp Diol Med 142:106-111, 1973). Moreover opioids can suppress Natural Killer (NK) cell activity (Beilin, B., et al. Brain Behav Immun 3:129-137, 1989). Also analgesics including buprenorphine can cause histamine release (Marone, G., et al. Int Arch Allergy Immunol 124:249-252, 2001; Stellato, C., Ann NY Acad Sci 406:32-47, 1995). Histamine is a well-known inflammatory mediator and plays a central role in the pathogenesis of allergic and inflammatory diseases by modulating vascular and airway response. Histamine has been shown to induce activation of human macrophages (Mozzoni, A., et al. J Immunol 170:269-2273, 1999), inhibit interferon alpha release from dendritic cells (Marone, G., et al., Int Arch Allergy Immunol, 124:249-252, 2001) and increase the synthesis and release of IL-10 from human macrophages (Sirois, J., et al. J. Immunol 164:2964-2970, 2000). Clearly, the analgesic-induced release of histamine would directly interfere with the inflammatory process. Studies by Piersman et al, (Lab Anim 33:328-333, 1999) provide an additional example of how analgesics may modify the expression of the disease process. These investigators, using an established murine model of endotoxemia, which showed that the opioids, fentanyl and buprenorphine, directly altered the outcome of their experiments by modulating the immune response. In this case, both opioids caused significant decreases in circulating levels of tumor necrosis factor alpha following administration of lipopolysaccharide (LPS).

This study is being conducted under the Animal Rule which allows for testing therapeutics in animals when tests cannot ethically be tested in humans and field efficacies tests are not feasible.

The pathogenesis of this infection is complex, involving a number of cell types and organs, and the assessment of efficacy is often measured by survival and reduction of clinical signs/symptoms. Therefore, in vitro techniques are insufficient to measure efficacy. Furthermore, for therapeutics aimed at licensure for the use of prophylactics against human disease, the path to FDA approval is unique. Controlled studies of clinical effectiveness in humans are impossible, since large groups of people are not typically exposed to these diseases. Instead of relying on human studies, the Animal Rule allows the FDA to approve drugs that are shown to be effective in two animal models, without clinical trials for effectiveness, under the following conditions:

-Human efficacy trials are not feasible or ethical
-Efficacy is shown in well understood animal models
-Efficacy is substantiated in multiple species
-Human clinical data on safety, toxicity and immunogenicity is still required

Therefore, the use of animals is a necessary means to support efficacy in therapeutics aimed at preventing human disease from many bioterrorism agents and lethal emerging infectious diseases. Furthermore, optimization of the ferret inhalation exposure is needed, as there are no known artificial replicas of the ferret lung.

Study 14: 10 Nonhuman Primates *(Chlorocebus aethiops)*

This study is classified as a Category E. It will evaluate how altering the time of treatment influences the efficacy of post-exposure treatment with the antibiotic in an animal model of infectious disease. This study will support future submissions to the FDA under the "Animal Efficacy Rule" amendment (21 CFR Parts 314 subpart I and 601 subpart H) to FDA's new drug and biological products regulations. The "Animal Efficacy Rule" applies when adequate and well controlled clinical studies in humans cannot be ethically conducted and field efficacy studies in humans are not feasible. The animal endpoints must clearly relate to the desired benefit in humans, generally the enhancement of survival or prevention of major morbidity. Therefore, it is necessary to challenge the animals with a dose of pathogen and follow the disease process in the untreated animals in order to determine the efficacy of the antibiotic. The giving of pain or stress relieving agents is contraindicated because it may interfere in determining the efficacy of the therapeutic. Furthermore, we need to study the natural progression of the disease process in the absence and presence of the therapeutic agent without the confounding influence of another agent on the pathophysiological process of animal infection. The illness experienced by animals exposed to the infectious agent must not be treated with analgesics because treatment will interfere with studying the pathogenesis of the disease. Exposed animals may experience seizures, severe depression, or coma; respiratory distress or severe dyspnea; persistent recumbency or extreme weakness; and weight loss. Importantly, the use of analgesics could alter the pathogenesis and immunologic response to infection, thus making it impossible to interpret the data obtained in this study. It is likely the use of analgesics will interfere with the accurate measurements of the disease process or with the antibiotic treatment whose efficacy is being assessed. Narcotic analgesics were shown to interfere with the mechanism(s) responsible for interferon production (Geher, W.F. et al., J. Toxicol Environ Health 2:577-582, 1977; Hung, C. Y. et. al. Proc Soc Exp Biol Med 142:106-111-1973). Moreover opioids can suppress Natural Killer (NK) cell activity (Beilin, B., et al., Brain Behav Immun 3: 129-137, 1989). Also, analgesics including buprenorphine can cause histamine release (Marone, G., et al Int Arch Allergy Immunol 124:249-252,

2001; Stellato, C., and Marone, G., Chem Immunol 62: 108-131, 1995) and respiratory depression (Soma, L.R., Ann NY Acad Sci 406: 32-47, 1995). Histamine is a well-known inflammatory mediator and plays a central role in the pathogenesis of allergic and inflammatory diseases by modulating vascular and airway responses.

Study 15: 78 Guinea Pigs *(Cavia porcellus)*
This study is classified as Category E. Organophosphate (OP) nerve agents are the deadliest of all classical chemical warfare agents, and can pose a significant health risk. The illness experienced by animals exposed to this agent must not be treated with analgesics because treatment will interfere with studying the pathogenesis of the disease. Once an animal is determined to be moribund, they will be placed on isoflurane to minimize additional pain and distress until euthanasia. It is inhumane to conduct therapeutic efficacy studies on humans with nerve agents or any agent that may result in death. The "Animal Efficacy Rule" applies when adequate and well controlled clinical studies in humans cannot be ethically conducted and field efficacy studies in humans are not feasible.

Study 16: 4 Nonhuman Primates *(Macaca fascicularis)*
This study is classified as Category E. The final definitive study involves the use of an infectious agent to do a final comparative (bridging study) comparing major surgery implanted to minimal surgically implanted telemetry used on selected infectious agent studies. As requested, this bridging study will confirm the ability to use a less surgically invasive telemetry system on infectious agent studies.
This study will support future submissions to the FDA under the "Animal Efficacy Rule" amendment (21 CFR Parts 314 subpart I and 601 subpart H) to FDA's new drug and biological products regulations. The "Animal Efficacy Rule" applies when adequate and well controlled clinical studies in humans cannot be ethically conducted and field efficacy studies in humans are not feasible. The animal endpoints must clearly relate to the desired benefit in humans, generally the enhancement of survival or prevention of major morbidity. Therefore, it is necessary to challenge the animals with a dose of pathogen and follow the disease process in the untreated animals. The giving of pain or

stress relieving agents is contra-indicated because it may interfere in characterizing the natural history of the disease. Exposed animals may experience seizures, severe depression, or coma; respiratory distress or severe dyspnea; persistent recumbency or extreme weakness, fever and weight loss. The illness experienced by animals exposed to the infectious agent must not be treated with analgesics as treatment will interfere with studying the pathogenesis of the disease. Importantly, the use of analgesics could alter the pathogenesis and immunologic response to infection, thus making it impossible to interpret the data obtained in this study. It is likely the use of analgesics will interfere with the accurate measurements of the disease process. Narcotic analgesics were shown to interfere with the mechanism (s) responsible for interferon production (Geher, W.F. et al., J. Toxicol Environ Health 2:577-582, 1977; Hung, C. Y. et. al. Proc Soc ExpmBiol Med 142:106-111-1973). Moreover opioids can suppress Natural Killer (NK) cell activity (Beilin, B., et al., Brain Behav Immun 3: 129-137, 1989). Also, analgesics including buprenorphine can cause histamine release (Marone, G., et al Int Arch Allergy Immunol 124:249-252, 2001; Stellato, C., and Marone, G., Chem Immunol 62: 108-131, 1995) and respiratory depression (Soma, L.R., Ann NY Acad Sci 406: 32-47, 1995).

Study 17: 5 Nonhuman Primates *(Chlorocebus aethiops)*

This study is classified as a Category E. It will evaluate how altering the treatment dose influences the efficacy of post-exposure treatment with the antibiotic in an animal model of infectious disease. This study will support future submissions to the FDA under the "Animal Efficacy Rule" amendment (21 CFR Parts 314 subpart I and 601 subpart H) to FDA's new drug and biological products regulations. The "Animal Efficacy Rule" applies when adequate and well controlled clinical studies in humans cannot be ethically conducted and field efficacy studies in humans are not feasible. The animal endpoints must clearly relate to the desired benefit in humans, generally the enhancement of survival or prevention of major morbidity. Therefore, it is necessary to challenge the animals with a dose of pathogen and follow the disease process in the untreated animals in order to determine the efficacy of the antibiotic. The giving of pain or stress relieving agents is contraindicated because it may interfere in determining the efficacy of the therapeutic. Furthermore, we need to study the natural progression of the disease process in the absence and presence of the therapeutic agent without the confounding influence of another agent on the pathophysiological process of animal infection. Clinical signs such as altered body temperature, respiratory rate and heart rate may be used to determine when euthanasia should be performed in order to diminish suffering before death. Exposed animals may experience fever, temperature decline, increase or decrease in heart rate, respiratory distress, seizures, weakness, and weight loss. The illness experienced by animals exposed to the infectious agent must not be treated with analgesics because treatment will interfere with studying the pathogenesis of the disease. Importantly, the use of analgesics could alter the pathogenesis and immunologic response to infection, thus making it impossible to interpret the data obtained in this study. It is likely the use of analgesics will interfere with the accurate measurements of the disease process or with the antibiotic treatment whose efficacy is being assessed. Narcotic analgesics were shown to interfere with the mechanism(s) responsible for interferon production (Geher, W.F. et al., J. Toxicol Environ Health 2:577-582, 1977; Hung, C. Y. et. al. Proc Soc Exp Biol Med 142:106-111-1973). Moreover opioids can suppress Natural Killer (NK) cell activity (Beilin, B., et al., Brain Behav Immun 3: 129-137, 1989). Also, analgesics including buprenorphine can cause histamine release (Marone, G., et al Int Arch Allergy Immunol 124:249-252, 2001; Stellato, C., and Marone, G., Chem Immunol 62: 108-131, 1995) and respiratory depression (Soma, L.R., Ann NY Acad Sci 406: 32-47, 1995). Histamine is a well-known inflammatory mediator and plays a central role in the pathogenesis of allergic and inflammatory diseases by modulating vascular and airway responses.

Study 18: 4 Guinea Pigs *(Cavia porcellus)*

This study is classified as Category E. Cough is a common clinical symptom and can be evoked by stimulating pulmonary small fibers in the airways. Actually, these fibers are nociceptive (pain sensitive) because they contain pain receptors, transient receptor potential V1 channel (TRPV1 receptors), that are also "cough receptors". This study is a pilot to develop an intra-tracheal instillation technique in GP and test whether intra-tracheal instillation of a drug will cause airway damage and pulmonary inflammation. Intra-tracheal instillation of this drug may induce airway damage or pulmonary inflammation with airway discomfort, but no analgesics will be used in order not to abrogate the evoked cough responses that will be the goal of this pilot study. Cough can be suppressed by analgesics. Therefore, the use of analgesics will make it impossible to interpret the data obtained in this study. Guinea pigs will be used because they share many of the features presenting in the control of cough in humans. Cough reflex is a complicated system including receptors, central respiratory network and respiratory muscles, these studies cannot be completed in the vitro and replaced by computer models.

Study 19: 12 Canines *(Canis lupus familiaris)*

This study is classified as Category E. The study will utilize a canine allergic dermatitis model in which dogs may be topically exposed to an allergen to which they have shown at least some level of sensitivity. This group would be expected to experience some level of irritation and distress due to the allergic skin reaction that occurs. Concurrent treatment with anti-inflammatory and analgesic drugs would invalidate the results obtained as they would directly affect the allergic response being studied. The behavioral response to the itch sensation will also be monitored. The use of sedatives would alter behavioral responses and invalidate these results as well. All dogs will be monitored for signs of pain and discomfort and any dog exhibiting severe or unrelenting pain and discomfort will be removed from the study and given the appropriate rescue therapy.

UNM HEALTH SCIENCES CENTER
OFFICE OF RESEARCH

Animal Resource Facility
Biohazard Compliance
Clinical Trials Center
Conflict of Interest
Human Research Protections
Office of Animal Care Compliance

The Institutional Animal Care and Use Committee has approved an exception to the standards and regulations of the Animal Welfare Act.

Summary:

A hamster breeding colony with a proven breeding record going back more than 20 years has been approved to group house 1 male and 2 females per cage during the breeding cycle. The cage floor space provided is 221 square inches, and includes the following enrichment: weekly supplements of fresh fruits and vegetables (e.g. apples, pears, lettuce, spinach, etc.) and ample nesting material along with standard rodent bedding. The success of the colony has prompted this exception and it affects an average of 58 hamsters in the colony.

Investigator Explanation:

Several mating pairs have been established and maintained for years and the Attending Veterinarian and Facility Supervisor have determined that the current housing arrangements meet the intent of the Act, which is to optimize enrichment while limiting aggression between breeders and minimizing cannibalism of neonates. Although there are references that cannibalism may increase when nursing hamsters are housed with other adult hamsters, based upon the procedures in the Biology ARF, with stable life-long mating groups, "life-mates", we have not seen any incident of cannibalism under this paradigm. If cannibalism should occur in a group then that group will be separated.

Reviewed and approved on March 20, 2013

NOV 20 2013